K020148

FEB 0 4 2002

**510 (k) Summary**

pHoenix ISE Reagents for Olympus® AU Chemistry Systems

Olympus® Diagnostics was the original manufacturer of the Olympus® AU Clinical Systems. Olympus® Diagnostics manufactures these products in Ireland and distributes through Olympus America Inc., which is located in Melville, NY.

pHoenix Diagnostics, Inc. is submitting a 510 (k) notification for the following: (1) pHoenix ISE Buffer, (2) ISE Internal Reference Solution and (3) ISE Low and High Standards. These ISE Reagents are intended for use on the ISE Module of the Olympus® AU Chemistry Systems. The ISE Buffer dilutes all measured patient samples for the quantitative determination of Na+, K+ and Cl- in serum by ISE. The ISE Internal Reference Solution is intended as a means of compensating for calibration drift in the quantitative determination of Na+, K+ and Cl- in serum samples on the Olympus AU Chemistry Systems. The ISE High and Low Standards are intended to provide calibration points for the Na+, K+ and Cl- Electrodes on the ISE system. pHoenix Diagnostics, Inc. is claiming substantial equivalence to predicate devices manufactured by Olympus® Diagnostics Corporation.

The products encompassed by this 510 (k) submission are Class I (75JJG) and Class II (75 JIX) In Vitro Diagnostic Solutions manufactured by pHoenix Diagnostics, Inc., 8 Tech Circle, Natick, MA 01760. These pHoenix ISE Reagents are intended to serve as direct replacements to like named products manufactured by Olympus® Diagnostics. Listed below are pHoenix products and their Olympus® Diagnostics equivalents.

| pHoenix Cat.# | Olympus Cat. # | Description | Models | Class |
|---|---|---|---|---|
| TBD | AUH1011 | ISE Buffer | AU | 1 |
| TBD | AUH1017 | ISE Internal Reference Solution | AU | 1 |
| TBD | AUH1014 | ISE Low Standard | AU | 2 |
| TBD | AUH1015 | ISE High Standard | AU | 2 |

pHoenix uses a similar composition, description and packaging design as that used by Olympus® Diagnostics in its products. pHoenix has shown performance equivalence of its products to Olympus® Diagnostics products in the following manner:

**510 (k) Summary cont.**

- Through a method comparison where results obtained on a Olympus® AU Chemistry Systems calibrated with pHoenix products and compared with results obtained on the same analyzer calibrated with Olympus® AU products; and

- Through a precision study where pHoenix products were installed on Olympus® AU Chemistry Systems and samples were measured over 20 runs.

A summary of the results of these studies follows:

Precision data was collected from the analysis of 2 levels of serum controls measured 2 runs per day, 2 times per run for 20 days on Olympus AU Systems for $Na^+$, $K^+$, and $Cl^-$ calibrated with pHoenix standard reagents. The NCCLS Guideline for precision evaluation, EP5-T, was followed. Typical Results are as follows:

Level 2

| Analyte | | N | Mean | STD | CV% | Min | Max |
|---|---|---|---|---|---|---|---|
| $Na^+$ | Total | 80 | 122 | 1.23 | 1.00 | 120 | 124 |
| | Run to Run | 20 | 122 | 0.67 | 0.55 | 121 | 123 |
| $K^+$ | Total | 80 | 4.6 | 0.105 | 2.26 | 4.4 | 4.8 |
| | Run to Run | 20 | 4.6 | 0.039 | 0.84 | 4.6 | 4.7 |
| $Cl^-$ | Total | 80 | 70.5 | 0.76 | 1.08 | 69 | 73 |
| | Run to Run | 20 | 70.5 | 0.30 | 0.42 | 70 | 71 |

Level 4

| Analyte | | N | Mean | STD | CV% | Min | Max |
|---|---|---|---|---|---|---|---|
| $Na^+$ | Total | 80 | 165 | 1.43 | 0.87 | 163 | 167 |
| | Run to Run | 20 | 165 | 0.61 | 0.37 | 164 | 166 |
| $K^+$ | Total | 80 | 6.50 | 0.062 | 0.96 | 6.4 | 6.6 |
| | Run to Run | 20 | 6.50 | 0.028 | 0.44 | 6.4 | 6.6 |
| $Cl^-$ | Total | 80 | 121 | 0.82 | 0.68 | 119 | 122 |
| | Run to Run | 20 | 121 | 0.47 | 0.39 | 120 | 122 |

**510 (k) Summary cont.**

Correlation with Olympus Diagnostics Standard Reagents

Correlation data was collected from 50 samples (patient serum samples, control samples and spiked samples) for $Na^+$, $K^+$, and $Cl^-$, measured on Olympus AU Clinical Chemistry Systems installed with pHoenix reagents (ISE Diluent, ISE Internal Reference Solutions and Standards) as compared with Olympus reagents separately. A Linear Regression Analysis was performed using pHoenix data as the independent X Variable and Olympus Data as the Dependent Y Variable in the equation $Y = a + bX$ . Typical results are as follows:

| Analyte | N | Slope | Intercept | Correlation Coefficient | Range |
|---|---|---|---|---|---|
| Na+ | 50 | 1.06 | -4.9 | 0.998 | 100 – 180 |
| K+ | 50 | 1.03 | 0.11 | 0.999 | 3 – 10 |
| Cl- | 50 | 0.98 | 4.8 | 0.997 | 70 – 150 |

I hope you find this information useful and informative.

Ram Nunna, President

1/14/02
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 0 4 2002

Mr. Ram Nunna
President
Phoenix Diagnostics, Inc.
8 Tech Circle
Natick, MA 01760

Re: k020148
Trade/Device Name: pHoenix ISE Reagents for Olympus® AU Chemistry Systems
Regulation Number: 21 CFR 862.1170; 21 CFR 862.1665; 21 CFR 862.1600
Regulation Name: Chloride test system; Sodium test system; Potassium test system
Regulatory Class: Class II; Class II; Class II
Product Code: CGZ; JGS; CEM
Dated: January 14, 2002
Received: January 16, 2001

Dear Mr. Nunna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT

**510(k) Number** (if known): K020148

**Device Name**: pHoenix ISE Reagents for Olympus® AU Chemistry Systems

**Indications For Use**:

**Intended Use:**

The pHoenix ISE Reagents for Olympus® AU Chemistry Systems are intended for use as ISE Reagents for the determination of $Na^+$, $K^+$, and $Cl^-$ for the Olympus® AU Clinical Chemistry Systems.

The ISE Buffer is intended for use as a diluent for patient samples for the quantitative determination of $Na^+$, $K^+$ and $Cl^-$ in serum by ISE.

The ISE Internal Reference Solution is intended as a means of compensating for calibration drift in the quantitative determination of $Na^+$, $K^+$ and $Cl^-$ in serum samples on the Olympus® AU Chemistry Systems.

The ISE High and Low Standards are intended to provide calibration points for the $Na^+$, $K^+$ and $Cl^-$ Electrodes on the Olympus® AU ISE systems.

Alan Cooper

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510(k) K020148

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)